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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,483	01/30/2004	Robert E. Clark	Duby/Clark-CIP	8748
22536 7590 01/24/2007 KNECHTEL, DEMEUR & SAMLAN 525 W. MONROE STREET, SUITE 2360 CHICAGO, IL 60661			EXAMINER HAND, MELANIE JO	
			ART UNIT 3761	PAPER NUMBER

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/769,483

Applicant(s)

CLARK, ROBERT E.

Examiner

Melanie J. Hand

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3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-17 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-17 and 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments, see Remarks, page 8, filed November 7, 2006, with respect to the objection to claims 1, 9-11 and 13-19 have been fully considered and are persuasive. The objection of claims 1, 9-11 and 13-19 has been withdrawn.

Applicant's arguments with respect to claims 1-19 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

The indicated allowability of claims 20-22 is withdrawn in view of the newly discovered reference(s) to Einstein. Rejections based on the reference follows.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 6, 7, 10-16 and 20-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,719,716. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a fluid irradiating apparatus comprising a housing, an irradiation station, cuvette, ultraviolet light source, means for receiving fluid transported, means for enclosing said cuvette and irradiation station and means for energizing the UV sources, and method of using, wherein the means for receiving, enclosing and energizing set forth in the respective disclosures are identical.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8, 10-17 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nitsch (U.S. Patent Application Publication No. 20020082669) in view of Einstein (U.S. Patent No. 6,951,548).

With respect to **claim 1**: Nitsch teaches a fluid irradiation apparatus for the modification of viruses and bacteria, comprising: a housing 78 having an exterior side and an interior side, the interior side further defining an enclosure ('669, Fig. 6); an irradiation station (indicated generally at 77) affixed to the housing 78 ('669, Fig. 7); a cuvette 80 positioned across the irradiation station 77 ('669, Fig. 7); an ivac bottle for drawing and transporting fluid through the cuvette 80 ('669, ¶20); means 51 for receiving the fluid transported and irradiated through the cuvette as such means is defined in the instant disclosure ('669, ¶20); means for enclosing the cuvette 80 and irradiation station 77 when the fluid irradiation apparatus is in use for minimizing the escape

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of ultraviolet light radiation that is considered herein to be an "equivalent thereof" of the means set forth in the disclosure according to 35 U.S.C. 112, sixth paragraph; and means for energizing the fluid irradiation apparatus in the form of an on/off switch. ('669, Fig. 6, ¶22)

Nitsch teaches one elongated UV light source 73 and thus does not teach at least two ultraviolet light sources positioned adjacent to the cuvette 80. Einstein teaches a blood irradiating apparatus having an irradiation station with at least two UV light sources 40 positioned adjacent a cuvette 200. Einstein teaches that having a plurality of separate sources 40 (in an elongate configuration similar to the source taught by Nitsch) allows for configuration of the sources to each provide a different wavelength and intensity of radiation to irradiate a variety of viral and bacterial diseases, thus it would be obvious to one of ordinary skill in the art to modify the device taught by Nitsch so as to contain at least two elongate UV sources as taught by Einstein to provide the ability to irradiate a variety of viral and bacterial diseases. ('548, Col. 4, lines 6-12)

With respect to **claim 2**: The cuvette 80 is made of a quartz crystal material. ('669, ¶¶18,21)

With respect to **claim 3**: Nitsch teaches that any material transparent to UV radiation can be used, thus Nitsch is inherently describing a cuvette 80 made of a durable plastic material. ('669, ¶18)

With respect to **claim 4**: Einstein teaches in Fig. 10 that the at least two UV sources 40 are, when in use, positioned on opposite sides of the cuvette 200.

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With respect to **claim 5**: Nitsch teaches that UV source 73 is mounted in a cover 77, but does not teach another UV source mounted in the enclosure defined by housing 70. Einstein teaches in Fig. 10 a UV source 40 mounted in a cover 22. ('548, Col. 3, lines 64-66)

With respect to **claim 6**: Nitsch teaches that UV source 73 is calibrated in the UV-B bandwidth, but does not teach at least two sources calibrated in the bandwidths set forth in claim 6. Einstein teaches that the at least two sources 40 are calibrated to a variety of UV bandwidths, which are considered herein to include UV-B. Thus the combined teaching of Nitsch and Einstein teaches at least two UV sources calibrated in at least the UV-B bandwidth.

With respect to **claim 7**: Nitsch teaches that source 73 has a relatively high UV-B output, i.e. at least a portion is calibrated in the UV-B bandwidth therefore Nitsch teaches that light source 73 is calibrated between 315-280 nm. The combined teaching of Nitsch and Einstein therefore teaches at least two UV sources that are calibrated between 40 and 400 nm. ('669, ¶18)

With respect to **claim 8**: The means taught by Nitsch for drawing and transporting fluid through the cuvette is by a peristaltic pump. ('669, ¶20)

With respect to **claim 10**: The means taught by Nitsch for receiving the fluid transported and irradiated through the cuvette is a bottle 51. ('669, ¶20)

With respect to **claim 11**: The means taught by Nitsch for enclosing the cuvette 80 and irradiation station 77 when the fluid irradiation apparatus is in use is the cover 78.

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With respect to **claim 12**: Apparatus 30 taught by Nitsch further comprises three switches as seen in Fig. 6, and teaches an ultraviolet light control switch ('669, ¶22), but does not explicitly teach that the other two switches are an on/off power switch or an on/off pump control switch. Einstein teaches a number of switches 76 provided to automate different processes of the blood irradiating apparatus 10 for example, the activation or intensity of individual lamps (i.e. a UV light control switch) and the flow velocity of the blood through the cuvettes 200, 300 (i.e. an on/off pump control switch). The combined teaching of Nitsch and Einstein is considered herein to be implicitly teaching a third switch that is an on/off power switch. ('548, Col. 5, lines 17-22)

With respect to **claim 13**: Nitsch teaches a fluid irradiation apparatus for the modification of viruses and bacteria contained in fluid, comprising: a housing 78 having an exterior side and an interior side, the exterior side further defining an aperture 84 and the interior side further defining a hollow center ('669, Fig. 6, ¶23); a cuvette 80 positioned across substantially the surface area of the aperture 84 and aligned in a substantially parallel relationship with the housing 78 ('669, Fig. 6); a first ultraviolet light source 73 located within the hollow center of the interior side of the housing 73 and positioned parallel to the cuvette 80; means 51 for receiving the fluid transported through the cuvette 80; means for transporting the fluid through the cuvette into the means for receiving the fluid in the form of a vacuum bottle or peristaltic pump ('669, Fig. 6, ¶23); means for returning the fluid back through the cuvette 80 at a controlled rate of flow from the means for receiving the fluid 51 that is considered herein to be an "equivalent thereof" of the means set forth in the disclosure according to 35 U.S.C. 112, sixth paragraph ('669, Fig. 6, ¶23).

Nitsch also does not teach a second ultraviolet light source located within the chamber. Einstein teaches at least two ultraviolet sources. Einstein teaches that having a plurality of separate sources 40 (in an elongate configuration similar to the source taught by Nitsch) allows

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for configuration of the sources to each provide a different wavelength and intensity of radiation to irradiate a variety of viral and bacterial diseases, thus it would be obvious to one of ordinary skill in the art to modify the device taught by Nitsch so as to contain at least two elongate UV sources as taught by Einstein to provide the ability to irradiate a variety of viral and bacterial diseases. ('548, Col. 4, lines 6-12)

Nitsch teaches a lens 74 for covering the first ultraviolet light source but does not teach a second ultraviolet light source or a lens for covering said second source. Einstein teaches at least two ultraviolet sources, thus the combined teaching of Nitsch and Einstein teaches at least two UV sources having a lens for covering said source. Thus the combined teaching of Nitsch and Einstein teaches at least two UV sources whereby, the fluid transferred through the same cuvette is irradiated in at least two separate instances by both the first and second ultraviolet light sources.

With respect to **claim 14**: Apparatus 30 taught by Nitsch further comprises a means for drawing the fluid through the cuvette 80 in the form of either a peristaltic pump or an ivac bottle. ('669, Fig. 6, ¶20)

With respect to **claim 15**: The combined teaching of Nitsch and Einstein teaches a means for enclosing a cuvette when the fluid irradiation apparatus is in use in the form of a cover, as seen in Fig. 10 of Einstein.

With respect to **claim 16**: Apparatus 30 taught by Nitsch further comprises a means for controlling the operation of the fluid irradiation apparatus in the form of a UV light control switch as seen in Fig. 6. ('669, ¶22)

With respect to **claim 17**: Apparatus taught by Nitsch further comprises a faceplate 74 that is fitted within the aperture in the exterior side of the housing. ('669, Fig. 6, ¶22)

With respect to **claim 19**: The second ultraviolet light source 40 taught by Einstein is positioned, when in use, on the opposite side of the cuvette 200 from the first ultraviolet light source 40 as seen in Fig. 10.

With respect to **claim 20**: Einstein teaches a method for modifying viruses and bacteria from fluid in the body, comprising the steps of: (a) providing a fluid irradiation apparatus 10 consisting of a housing 80 and an irradiation station 20 in the housing; (b) removing fluid from the body and depositing the fluid into a conduit 50; (c) transporting the removed fluid from the body along the conduit 50 and into a cuvette 200; (d) irradiating the removed fluid at the irradiation station 20 within the cuvette 200 by at least two ultraviolet light sources 40; (e) transporting the irradiated fluid from the cuvette 200 along the conduit 50 and depositing the irradiated fluid into a container 62.

Einstein does not teach step (f), removing the irradiated fluid from the container 62 and depositing the fluid back into the conduit. However since Einstein teaches a pump 66 which transports blood through apparatus 10 and the treated blood necessarily must be returned to the patient, i.e. step f) is known in the art, it would be obvious to one of ordinary skill in the art to utilize the pump taught by Einstein to remove irradiated fluid from said container and deposit said fluid back into conduit 50. ('548, Col. 4, line 62 – Col. 5, line 4)

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With respect to **claim 21**: Einstein teaches the step of directing UV radiation from the at least two UV light sources 40 at the cuvette 200. ('548, Col. 4, lines 24-27)

With respect to **claim 22**: Einstein teaches a method for modifying viruses and bacteria from fluid in the body, comprising the steps of: (a) transporting fluid through a conduit 50 into a cuvette 200; (b) providing a plurality of ultraviolet light sources 40 at the cuvette 200; (c) irradiating the fluid in the cuvette 200 as it passes the plurality of ultraviolet light sources 40 to produce a first irradiated fluid.

Einstein does not explicitly teach steps d) and e). However since Einstein teaches a pump 66 which transports blood through apparatus 10 and the treated blood necessarily must be returned to the patient, i.e. steps d) and e) are known in the art, it would be obvious to one of ordinary skill in the art to utilize the pump taught by Einstein to reverse the directional flow of the fluid to pass back through the same cuvette 200, thereby irradiating the first irradiated fluid as it again passes the plurality of ultraviolet light sources 40 a second time to produce a second irradiated fluid in order to return treated blood back to the patient to provide the benefit of such treatment to said patient. ('548, Col. 4, line 62 – Col. 5, line 4)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

January 11, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', with a long, sweeping horizontal stroke extending to the right.